

REMARKS

Claims 3-5, 9-12, 34, 39, 40, 46, 47, 62, 63, 65, 70 and 81-84 are pending in the application. Claims 3 and 34 have been amended. Claims 40, 46, 47, 63, 65, 70 and 81-84 have been cancelled without prejudice as being directed to non-elected inventions. Accordingly, once the amendments presented herein have been entered, claims 3-5, 9-12, 34, 39 and 62 will remain pending. No new matter has been added.

Rejection of Claims 3-5, 9, 10-12, 34, 39, and 62 Under 35 U.S.C. 112

The Examiner has rejected claims 3-5, 9-12, 34, 39 and 62 under 35 USC 112, first paragraph as being indefinite for failing to particularly point out and distinctly claim the invention. Applicants disagree. However, in the interest of expediting prosecution, Applicants have amended the claims to more clearly indicate what is being claimed.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 3-5, 9-12, 39 and 62 Under 35 U.S.C. 102(b) and (e)

The Examiner has rejected claims 3-5, 9-12, 39 and 62 as being anticipated by US Patent No.: 5,650,291. Specifically, the Examiner indicates that the '291 patent discloses a method of determining if a subject has ovarian cancer by detecting CA 215 which has a molecular mass of 60kD.

While in no way acquiescing to the validity of the Examiner's rejection and solely in the interest of expediting prosecution, Applicants have amended the claims, thereby rendering this rejection moot.

Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

Rejection of Claims 3-5, 9-12, 39 and 62 Under 35 U.S.C. 102(e)

The Examiner has rejected claims 3-5, 9-12, 39 and 62 as being anticipated by US Patent Application Publication No.: 2003/0003479. Specifically, the Examiner indicates that the '479 publication discloses methods for detecting, characterizing and staging ovarian cancers comprising correlating changes in levels of expression of marker **genes** with the presence of ovarian cancer. Applicants respectfully traverse this rejection.

This '479 publication does not anticipate the pending claims for at least two reasons. First, the markers disclosed in the '479 application are nucleic acid markers and not polypeptide markers. The '479 application does not teach or suggest the identification and/or quantitation of protein biomarkers. Second, the markers disclosed in the '479 application are not the same as those set forth in the instant claims.

The '479 Application teaches the use of nylon arrays to identify nucleic acid molecules that are differentially expressed in cancerous ovarian cell samples when compared to non-cancerous ovarian cell samples. Table 1, which is cited by the Examiner, sets forth the marker genes for which significant increases in the level of expression was observed. The '479 publication does not teach or suggest that proteins corresponding to the identified nucleic acid molecules are differentially expressed. In fact, the publication focuses solely on methods directed to identifying differentially expressed nucleic acid molecules. Therefore, the '479 publication does not anticipate the use of protein biomarkers for ovarian cancer, let alone the specific markers set forth in the instant claims.

Secondly, even if, *arguendo*, the '479 publication did teach protein biomarkers for the detection of ovarian cancer, none of the nucleic acid markers disclosed correspond to the protein biomarkers set forth in the pending claims. The Examiner indicates that

Markers O49 and O82 have molecular weights synonymous with the Applicants' markers, Marker IV (39.8kD) and Marker V (54kD),

Marker O316 (58kD) has a molecular weight of about 54kD and 60kD, which correspond to markers V and VI,

Marker O426 (52kD) and O452 (36kD) have molecular weight of about Marker V (54kD) and Marker IV (39.8kD),

Markers O504 (58kD), O512 (40kD) and O517 (72kD) are within the range of Applicants' markers V, IV, and VII.

Applicants respectfully traverse this rejection. As previously stated, the makers identified in the instant application are protein biomarkers. The markers cited by the Examiner are proteins that correspond to nucleic acid markers identified in the '479 publication.

Applicants specification teaches that the protein biomarkers set forth in the specification were identified using a method of mass spectroscopy known as SELDI. Those of skill in the art know that the molecular weight of proteins determined by SELDI is very precise. Specifically, the mass accuracy of SELDI-TOF-MS as given by the manufacturer is less than 0.1% (<1 Da per 1000 Da) (see, Schaub et al., American Journal of Transplantation. 5(4):729-738, April 2005).

The Examiner has cited proteins that have masses that are from 0.5% to 14.5% different from the masses of the protein biomarkers identified by Applicants. Accordingly, the protein biomarkers that correspond to the nucleic acid biomarkers set forth in the '479 publication do not correspond to the biomarkers set forth in the instant application.

Accordingly, based on the foregoing, the '479 publication does not anticipate the pending claims, and Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

Rejection of Claims 3-5, 9-12, 39 and 62 Under 35 U.S.C. 103(a)

The Examiner has rejected claims 3-5, 9-12, 39 and 62 as being unpatentable over US Patent Application Publication No.: 2003/0003479 in view of US Patent Application Publication No.: 2004/0137106 and US Patent 5,650,291.

As indicated above, the '479 publication does not teach or suggest the use of protein biomarkers for the detection of ovarian cancer, and the proteins that correspond to the nucleic acid biomarkers of the '479 publication are not the same molecular weights as the biomarkers in the instant claims.

The '106 publication and the '291 patent do not make up for the deficiencies of the '479 publication. Accordingly, the combination of these documents would not put one of skill in the art in possession of the instant invention.

Therefore, Applicants respectfully request the reconsideration and withdrawal of the foregoing rejection.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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